DEC 21 2004

K043130

510(k) Summary of Safety and Effectiveness

Submitter Information:

PAJUNK GmbH
Karl Hall Straße 1
D78187 Geisingen
Germany

USA Contact:

Mr. Burk A. Brandt
CE Consultancy, Inc.
5010 NW Crescent Valley Dr.
Corvallis, OR 97330 – USA
Phone: (541) 752-3953
Fax: (541) 752-3972

Device Name:

Trade Name: Stimulong Plus Catheter Sets
Plexalong Sets
Unipolar Needles
Common Name: Anesthesia Conduction Kit
Anesthesia Conduction Needle (W/Wo Introducer)
Classification Name: Anesthesia Conduction Kit (Reference, 21CFR, 868.5140, April 1, 2003), Anesthesia Conduction Needle (Reference, 21CFR, 868.5140, April 1, 2003)

Predicate Devices:

The Stimulong Plus Catheter sets and Plexalong sets consist of a Pajunk Unipolar needle (conduction cannula with nerve stimulus connector and tubing), and an open ended conduction catheter and a catheter adapter. The catheter in the Stimulong Plus Catheter is the same as the catheter in the Plexalong sets except for the conductive ring tip. The Stimulong Plus Catheter sets have been cleared for market by the FDA under 510(k) number K033018. The Plexalong sets have been cleared under K013041 and the Unipolar needles under 510(k) number K000722 (facet and Sprotte tip conduction cannula and tubing). Unipolar needles with a Tuohy tip were cleared for market under 510(k) number K023218.

The packaging materials used to package the Stimulong Plus Catheter, Pajunk Plexolong sets, and cannula has not changed. The contract sterilizer, other than a company name change (was Griffith Micro Science, now Sterigenics) and sterilizing process is the same.

Device Description:

The Pajunk Stimulong Plus Catheter Sets and Plexalong sets are single use, sterile, non-pyrogenic and latex free conduction anesthesia sets intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. The Stimulong Plus Catheter sets and Plexalong sets consist of a single use sterile, non-pyrogenic conduction needle with tubing, a catheter and catheter adapter. The catheter in the Stimulong Plus Catheter is the same as the catheter in the Plexalong sets except for a conductive ring tip. Continuous delivery is accomplished using the catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the tip of the conduction needle and after placement of the conduction catheter (Stimulong Plus catheter) to its tip via the catheter adapter.

Intended Use:

The Pajunk Stimulong Plus Catheter Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction catheter to its tip via the catheter adapter.

Technology Characteristics:

Except for the insulating material used to coat the needles, the Pajunk conduction cannula, including the physical dimensions, connector, tubing, metal and plastics, have been cleared under 510(k) numbers K000722, K013041 and K023218. The materials used to manufacture the Pajunk catheter and catheter adapter except for the conductive catheter tip and wire are identical to the materials used to manufacture the catheter and catheter adapter of the predicate devices described earlier in this *510(k) Summary of Safety and Effectiveness.* Biocompatibility testing of the conductive tip, wire and alternate plastic material is located in *Section 7* of this submission. Use of a conduction catheter was cleared by FDA under 510(k) No. K030937. The Stimulong Plus Catheter Sets are supplied in polypropylene containers that are sealed to assure sterility.

Summary of Performance Testing

The Pajunk Stimulong Plus Catheter Sets were designed to conform to the applicable sections of the following recognized consensus standards. The testing included verifying conformance to these standards.

Standard	Issue Date	Title
DIN 13090/ISO 594	08.1984	Luer fittings w/wo locking feature
DIN 13097 Part 1	01.1980	Medical injection cannula
DIN 13097 Part 3	11.1979	Medical cannula
DIN 17442/ISO 9626	10.1977	Steel for medical instruments
DIN EN 550	07.1993	Sterilization of med. Prod.; Validation & routine controls for sterilization with ETO
DIN EN 556	01.1995	Sterilization of medical products, requirements for medical products that are labeled "sterile"
DIN EN 724	12.1994	Guidance on the application of EN29001 and EN46001 for non-active medical products
PrEN 868-1	10.1996	Packaging materials for the sterilization of packaged goods. Part 1: general requirements for the validation of the packaging of sterilized end-packaged products
DIN EN 868-2	03.1993	Packaging materials for the sterilization of packaged goods. Part 2: sterilization packaging, requirements and tests.
DIN EN 980	08.1996	Graphic symbols for marking medical products
DIN EN 1441	08.1994	Risk analysis for medical products
EN ISO 14971	2000	Risk Management
DIN EN 1707	01.1997	6% Luer cone connections for injection cannula and particular medical equipment
DIN EN/ISO 9626	06.1995	Cannula tube of non-rusting steel (SS) for the manufacture of medical products
DIN EN ISO 10993-1	08.2003	Biological evaluation of medical products – instructions for selection of tests
DIN EN 46001	12.1993	Particular requirements for medical products
DIN 17440	09.1996	Stainless Steels
BS 4843		Single entry IV cannula

Conclusion:

The PAJUNK Stimulong Plus Catheter Sets are as safe and effective as the predicate devices when used according to the instructions in the directions for use supplied with the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Pajunk GmbH
c/o Mr. Burk A. Brandt
President
CE Consultancy, Incorporated
5010 NW Crescent Valley Drive
Corvallis, Oregon 97330

Re: K043130
Trade/Device Name: Pajunk Stimulong Plus Catheter Sets
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSP
Dated: December 3, 2004
Received: December 6, 2004

Dear Mr. Brandt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043130

Device Name: **Pajunk Stimulong Plus Catheter Sets**

Indications For Use:

The Pajunk Stimulong Plus Catheter Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction cathter to its tip via the catheter adapter.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043130